

ARTICLE TYPE

Penalized Competing Risks Analysis using casebase sampling

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Abstract

In biomedical studies, quantifying the association between prognostic genes and markers with time-to-event outcomes is crucial for predicting a patient's disease risk based on their specific covariate profile. Modeling competing risks is necessary, as patients may face multiple mutually exclusive events, such as death from different causes. However, current methods for competing risks analysis often yield coefficient estimates that are difficult to interpret, making it challenging to connect them to event rates. Additionally, the high dimensionality of genomic data, where the number of variables exceeds the number of subjects, presents a significant challenge.

In this work, we propose a novel approach using an elastic-net penalized multinomial model within a casebased sampling framework to analyze competing risks survival data. We also introduce a two-step method called the de-biased case-base to improve the predictive performance regarding disease risk. Through a comprehensive simulation study that replicates biomedical data, we show that the casebase method is effective in variable selection and survival prediction, particularly in scenarios involving non-proportional hazards. Moreover, we highlight the flexibility of this approach in generating smooth-time incidence curves, which significantly improve the accuracy of patient risk estimation assessments.

KEYWORDS

keyword1, keyword2, keyword3, keyword4

1 | INTRODUCTION

In numerous clinical studies, a primary outcome frequently modeled is the time to an event of interest, or survival time during the study period. When every individual in a study experiences the event, various statistical methods can be applied effectively. However, analyzing survival data presents certain challenges: 1) Not all patients experience the event within the study timeframe, yet they remain at risk of doing so in the future, leaving their actual time to the event unknown. 2) Survival data are rarely normally distributed and often exhibit a skewed distribution.

Given these challenges, developing methods specifically tailored for survival data is essential. In typical survival or time-to-event analysis, the outcome variable indicates the time until one event of interest occurs. However, combined endpoints are a common extension that includes both the cause of interest and a competing risk. In this context, a competing risk is an event that prevents the primary event of interest from happening. For example, many medical studies consider 'disease-free survival,' defined as the time until either the recurrence of a disease or death (from a cause other than the disease), whichever occurs first. Here, while death due to the disease is our primary outcome, death from another cause is classified as a competing risk.

From a clinical perspective, the most important quantity for both clinicians and patients derived from survival analysis is the estimated risk of an event for patients with a particular covariate profile. This risk can be estimated through the cumulative incidence function (CIF), also known as absolute risk, which indicates the probability that a person at risk will experience the event of interest within a specified time frame.

One widely used method for analyzing a single endpoint in survival analysis is the Cox Proportional Hazards model. Its flexibility comes from its semi-parametric formulation, enabling inference about how covariates influence the hazard function without restricting the response to a specific parametric family. However, this flexibility has a drawback: the baseline hazard

is separated from the covariate effects, requiring separate estimation of the baseline hazard when calculating the cumulative incidence function. This results in stepwise survival risk estimates that can be difficult to interpret. Additionally, extending the Cox model to a competing risks scenario involves fitting separate models for each risk. This approach is limited because, although we can estimate cause-specific hazards, we cannot simultaneously estimate the cumulative incidence of the event of interest while accounting for competing risks.

To overcome these limitations, the Fine-Gray model was introduced as an alternative, directly modelling the impact of covariates on the cumulative incidence function. However, when assessing whether a particular risk factor is associated with the rate of outcome occurrence among event-free individuals, cause-specific hazards remain relevant, which this model does not readily provide. Furthermore, certain combinations of covariates in the Fine-Gray model can produce cumulative incidence probability estimates exceeding 1. In fact, in modelling competing risks, existing approaches typically focus on cause-specific hazards or cumulative incidence functions. Since comprehensive competing risks survival analysis requires both, estimating one from the other with current models is not straightforward.

As survival data, particularly high-dimensional data, become more prevalent, there is a growing need for a competing risks model that can effectively handle cause-specific hazards, produce smooth and interpretable estimates of the cumulative incidence function, and be adaptable for high-dimensional data settings and scenarios involving time-varying covariates. Therefore, we propose using a multinomial model combined with casebase sampling to fit fully parametric hazard models. This approach provides smooth hazard and cumulative incidence function estimates, and our application of multinomial regression enables access to the desirable properties of the generalized linear model family, including regularisation-based variable selection.

This paper shows that the multinomial model with casebase sampling exhibits strong variable selection in both low- and high-dimensional data, while effectively predicting cumulative risk, making it a viable option for comprehensive competing risks analysis. The structure of this paper includes an explanation of the casebase framework and its multinomial implementation, along with the debiasing step. It then presents the results of our simulation experiments, focusing on variable selection and prediction performance, and explores the model's ability to estimate the cumulative incidence function by debiasing the casebase model. Subsequently, this model is applied to the xxxx dataset to evaluate its performance in real-world medical data. Finally, the paper discusses the limitations, potential extensions of the approach, and suggestions for future research.

2 | METHODS

2.1 | Casebase Framework

In a competing risks setting, we model the occurrence of different event types using counting processes. Let $N_{0j,i}(t)$ be the counting process for individual i and event type j . This process is equal to 1 if individual i transitions from a starting state (state 0) to event state j within the time interval $[0, t]$, and 0 otherwise. The history of the process for individual i up to time t is denoted by $\mathcal{H}_i(t-)$. The expected differential change in the counting process relates to the cause-specific hazard function, $\alpha_{ij}(t)$, through the following expression

$$E[dN_{0j,i}(t)|\mathcal{H}_i(t-)] = I(T_i \geq t, J_i = j)\alpha_{ij}(t)dt.$$

The casebase sampling framework was formally proposed for fitting smooth-in-time functions. It extends methods used in case-control studies. This framework considers an entire study base, which is the total of all individual follow-up times, or person-time. The study base consists of person-moments. A person-moment is defined as a specific point in time, t , and the individual's corresponding prognostic value at that time.

From the study base, two series are generated: a case series and a base series. The case series includes all person-moments where an event of interest occurred. The base series is made up of a representative sample of person-moments, called controls, taken from the study base. These person-moments are sampled by first selecting an individual i with probability $\phi_i = B_i/B$, where B_i is the total person-time contributed by individual i , and B is the total person-time in the study. A person-moment b_j is then sampled uniformly from that individual's follow-up time, a process that can be modelled as $b_j \sim \text{Unif}(0, B_i)$. An individual might contribute multiple person-moments to the base series.

The fundamental idea of casebase sampling is comparing person-moments when events occurred (the cases) with person-moments when individuals were at risk of the event (the bases). This method of representative sampling differs from the risk-set sampling used in Cox regression and aims to capture the entire baseline hazard. A key benefit of this approach is its capacity to

directly estimate cause-specific hazard functions, which then enables the derivation of smooth-in-time survival and cumulative incidence functions.

To estimate the parameters, we revisit the counting process framework. The cause-specific hazard function for event j and individual i is parameterized using a vector of coefficients, β_j , and time, t , denoted as $\alpha_{ij}(t; \beta_j)$. According to the relationship established for counting processes, the differential change in the cause-specific hazard functions for individual i at time-to-event T_i satisfies

$$\alpha_{ij}(t; \beta_j)dt = E[dN_{0j,i}(t)|\mathcal{H}_i(t-)]$$

This provides the foundation for building the likelihood and estimating functions for the model parameters.

2.2 | Multinomial Parameterization, Regularization and Optimization

We can construct a multinomial logistic model for the casebase likelihood. We use Y_i to denote a categorical response variable. Let us define Y_i to have three levels for the case of two competing events, i.e., 0,1,2, where the total number of competing events is two. The likelihood function can be written as:

$$\log \left(\frac{\Pr(Y = j|X_i)}{\Pr(Y = 0|X_i)} \right)$$

where class 0, i.e., the censored individuals, serves as the reference class. The likelihood is defined for a set of covariates X_i for individual i .

In terms of optimizing a penalized likelihood, the glmnet package has implemented fast algorithms for several generalized linear models, including multinomial regression with the elastic-net family penalty. However, the glmnet package uses a symmetric parameterization of the multinomial model. This parameterization estimates the relative differences between classes rather than the absolute probabilities for each class, resulting in the constant offset term not being fitted. Since the case base approach relies on the constant offset of the intensity function, we need a penalized model using the multinomial logistic parameterization. Developing a function to fit and tune this penalized model is a key contribution of this work.

The penalized multinomial logistic regression is fitted using accelerated stochastic variance reduced gradient descent (ASVRG), as this algorithm shows fast convergence for high-dimensional datasets with a larger number of predictors than observations ($p > n$). This accelerated method combines SVRG's variance reduction with momentum to speed up convergence (@DriggsEhrhardtSchonlieb:2022). Like SVRG, this algorithm begins with a full-batch gradient computation. However, instead of relying solely on stochastic updates, it employs a sequence of extrapolated points, constructed as a weighted combination of the current and previous iterations.

Here, we denote $l(\beta)$ as the joint likelihood across all individuals $i = 1, \dots, n$ and causes $j = 1, 2$, i.e., $\sum_{i=1}^n \sum_{j=1}^2 \log(\frac{\Pr(Y_i=j|X_i)}{\Pr(Y_i=0|X_i)})$. For covariates $k \in \{1, \dots, p\}$, we can estimate the coefficient matrix η as

$$\hat{\beta} = \arg \max_{\beta} \{l(\beta) + \lambda \sum_{k=1}^p w_k \left(\frac{1-\phi}{2} \right) \sum_{j=1}^2 \beta_{kj}^2 + \phi \sum_{j=1}^2 |\beta_{kj}|\}.$$

ϕ is the mixing parameter between the LASSO and ridge penalties. Setting $\phi = 1$ and $\phi = 0$ corresponds to the LASSO and ridge penalties, respectively. w_k represents the penalty factor for the k^{th} covariate, allowing parameters to be penalized differently. In this work, the penalty factor for the intercept and for time is set to 0, so they are unpenalized and always included in the model. Solving for the coefficients η will produce a matrix of size $(p+1) \times 2$, where the j^{th} column corresponds to the coefficients for cause j , for $j = 1, 2$.

A cross-validation function was also implemented to fine-tune the shrinkage parameter λ . The tuning relies on the multinomial deviance as the measure of model goodness-of-fit, shown below:

$$-2 \sum_{i=1}^n \sum_{j=1}^2 \log \left(\frac{\Pr(Y_i = j|X_i)}{\Pr(Y_i = 0|X_i)} \right).$$

Algorithm 1 Pseudocode for our algorithm

```

for e do each frame
  for w do water particles  $f_i$ 
    compute fluid flow?
    compute fluid-solid interaction?
    apply adhesion and surface tension?
  end for
  for s do liquid particles  $s_i$ 
    for n do neighboring water particles  $f_j$ 
      compute virtual water film
    (see Section ??)
    end for
  end for
  for s do liquid particles  $s_i$ 
    for n do neighboring water particles  $f_j$ 
      compute growth direction vector
    (see Section ??)
    end for
  end for
  for s do liquid particles  $s_i$ 
    for n do neighboring water particles  $f_j$ 
      compute  $F_\theta$  (see Section ??)
      compute  $CE(s_i, f_j)$ 
    (see Section ??)
    if then  $CE(b_i, f_j) > \text{glaze threshold}$ 
       $j\text{th water particle's phase} \leftarrow \text{ICE}$ 
    end if
    if then  $CE(c_i, f_j) > \text{icicle threshold}$ 
       $j\text{th water particle's phase} \leftarrow \text{ICE}$ 
    end if
  end for
end for

```

4 | CONCLUSIONS

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AUTHOR CONTRIBUTIONS

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ACKNOWLEDGMENTS

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FINANCIAL DISCLOSURE

None reported.

CONFLICT OF INTEREST

The authors declare no potential conflict of interests.

SUPPORTING INFORMATION

Additional supporting information may be found in the online version of the article at the publisher's website.

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APPENDIX

A PROGRAM CODES APPEAR IN APPENDIX

Using the package `listings` you can add non-formatted text as you would do with `\begin{verbatim}` but its main aim is to include the source code of any programming language within your document.

Use `\begin{lstlisting}... \end{lstlisting}` for program codes without mathematics.

The `listings` package supports all the most common languages and it is highly customizable. If you just want to write code within your document, the package provides the `lstlisting` environment; the output will be in Computer Modern typewriter font. Refer to the below example:

LISTING 1 Descriptive caption text

```
for i:=maxint to 0 do
begin
{ do nothing }
end;
Write('Case insensitive ');
WriteE('Pascal keywords.');
```

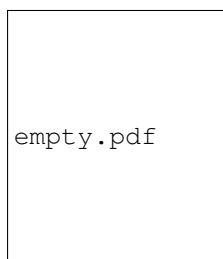
A.1 Subsection title of first appendix

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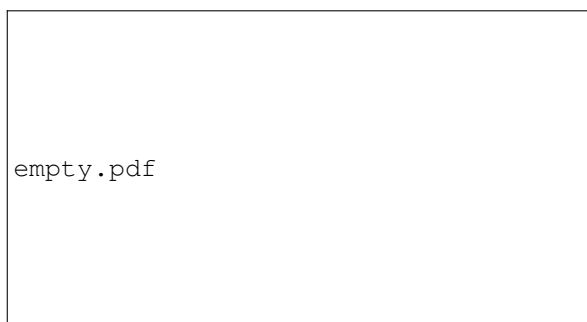


FIGURE B1 This is an example for appendix figure.

TABLE B1 This is an example of Appendix table showing food requirements of army, navy and airforce.

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Example for an equation inside appendix

$$\mathcal{L} = i\bar{\psi}\gamma^\mu D_\mu\psi - \frac{1}{4}F_{\mu\nu}^a F^{a\mu\nu} - m\bar{\psi}\psi \quad (\text{B1})$$

C EXAMPLE OF ANOTHER APPENDIX SECTION

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$$\mathcal{L} = i\bar{\psi}\gamma^\mu D_\mu\psi - \frac{1}{4}F_{\mu\nu}^a F^{a\mu\nu} - m\bar{\psi}\psi$$

(C2)

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